UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/127,738 | 08/03/98 | PONCE DE LEON F | 002076-005 |

HM22/0319

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| WILSON,M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1633 | 15 |

**DATE MAILED:** 03/19/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/127,738 | PONCE DE LEON ET AL. | |
| | Examiner | Art Unit | |
| | Michael Wilson | 1633 | |

*-- The MAILING DATE of this communication app ars on th cover sheet with th correspond nce addr ss --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Michael C. Wilson, Art Unit 1633.

Applicant's arguments filed 1-2-01, paper number 13, have been fully considered but are moot in view of the new rejections below. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-24 are pending and under consideration in the instant office action.

### *Claim Rejections - 35 USC § 112*

1. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) a method of isolating avian EG/ES cells comprising (i) isolating cells from the blastoderm of stage X avian embryos; and (ii) culturing the pure population of cells in media comprising LIF, bFGF, IGF and SCF in amounts sufficient to isolate and maintain EG/ES cells, 2) a method of making chimeric avians comprising (i) isolating a pure population of PGCs from the blood of stage 12-14 embryos; and (ii) culturing the pure population of PGCs in media comprising LIF, bFGF, IGF and SCF in amounts sufficient to maintain said PGCs; transferring said PGCs into a recipient avian embryo; and obtaining a germline chimeric avian that is not a somatic cell chimeric avian; and 3) a method of making chimeric avians comprising (i) isolating cells from the blastoderm of stage 12-14 embryos; and (ii) culturing the cells in media comprising

LIF, bFGF, IGF and SCF in amounts sufficient to maintain EG/ES cells; transferring said EG/ES cells into a recipient avian embryo; and obtaining a germline and somatic cell chimeric avian; 4) an EG/ES cell line made by the method of 1) above, does not reasonably provide enablement for 1) isolating EG/ES cells from blood isolated from stage 12-14 chicken embryos, 2) using PGCs isolated from the blood stage 12-14 chicken embryos to make germline and somatic cell chimeric avians, 3) stably transfecting EG/ES cells or PGCs, 4) making transgenic avians to isolate exogenous proteins (therapeutic or otherwise), 5) making transgenic avian with an altered phenotype, 6) EG/ES cells isolated from the blood of stage 12-14 embryos, 7) EG/ES cells transfected with an exogenous nucleic acid or 8) the EG cell line P102896 as in claim 24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-13 are directed toward a method of culturing a pure population of avian PGCs in a culture medium for a prolonged period. Claims 14-20 are directed toward an improved method of making chimeric avians. Claims 21-24 are directed toward an EG cell line. EG cells are being interpreted as cells that can become both germline and somatic cells (page 22, line 15) which is equivalent to ES cells known in the art.

Overall, the state of the art at the time of filing was such that it was unpredictable how to obtain cells from livestock species that produced somatic and germ cells were (ES cells) (Seamark, 1994, Reproductive Fertility and Development, Vol. 6, pages 653-657; see abstract).

However, Pain (Pain et al., 1996, Development, Vol. 122, pages 2239-2348) taught isolating cells from the blastoderm of a stage X chicken embryo, culturing the cells for more than 160 days in the presence of 10 ng/ml bFGF, 20 ng/ml IGF, 1% vol/vol SCF, 1% vol/vol LIF without feeder cells (page 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10; 2341, col. 2, paragraph 4). Contrary to applicants statement in the specification that Pain did not demonstrate the cells were ES cells (page 5, line 15); the cells of Pain expressed EMA-1 and were introduced into stage X chicken embryos to obtain germline and somatic cell chimeras (page 2341, col. 1, paragraph 2; page 2346, col. 2, line 8; Fig. 8). The cells of Pain are ES cells or EG cells because they are able to make germline and somatic cells chimeras. It is noted that the cells of Pain are also PGCs according to applicants definition because they express EMA-1 and are able to provide germline transmission. Confirmation is provided by Simkiss (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137) who teaches that stage X chicken embryos as used by Pain contain PGCs (page 111, Fig. 4.1, top panel). Thus, the only method known in the art at the time of filing that provided avian cells that became germline and somatic cells required that the cells be isolated from stage X embryos.

The specification does not teach how to isolate EG cells from PGCs that are isolated from the blood of stage 12-14 chicken embryos as disclosed in the instant invention. The specification teach isolating cells from embryonic blood of stage 12-14 chicken embryos (page 15, lines 3-8), transplanting the cells into stage X chicken embryos and obtaining germline chimeras that were

not somatic cell chimeras (page 35-36). Applicants do not provide any indication that PGCs isolated from the blood of stage 12-14 chicken embryos can become both germline and somatic cells. Applicants states SSEA-1, SSEA-3, MC-480 and EMA-1 antibodies are used to mark EG cells (page 21, line 20); however, the antibodies are not specific to EG cells as they also are used to mark PGCs that become germline cells but not somatic cells. Therefore, the specification does not teach how to isolate EG cells from PGCs that are isolated from the blood of stage 12-14 chicken embryos as disclosed in the instant invention. Given the teachings in the art taken with the guidance in the specification, it would have required one of skill undue experimentation to determine how to obtain avian cells that become both germline and somatic cells upon transplantation into embryos other than from stage X embryos as taught by Pain.

Claims 14-20 are directed toward a method of making a transgenic avian. The purpose of making a transgenic avian is to isolate exogenous proteins from the avian (page 7, line 17) or to change the phenotype of the bird (page 2, line 23). The specification teaches obtaining chimeric birds from wild-type birds, but such chimeras are only used to make more wild-type birds and do not result in a bird with a different phenotype or a bird expressing an exogenous protein. Therefore, the specification does not enable method claimed because the specification does not enable changing the phenotype of the birds or producing an exogenous protein in the birds.

In particular, claims 17-19 recite that the method requires transfecting the EG cells prior to transplantation into the host embryo and claim 23 recites an EG cell transfected with an exogenous transgene. The state of the art at the time of filing was such that the phenotype of

transgenic avians with an exogenous transgene was unpredictable. Wall (1996, Theriogenology, Vol. 45, pages 57-68) discloses the unpredictability of transgene behavior due to factors such as position effect and unidentified control elements resulting in a lack of transgene expression or variable expression (paragraph bridging pages 61-62). Thus, the level and the specificity of expression of a transgene is greatly dependent on the specific transgene construct used making the phenotype of transgenic animals unpredictable. The specification teaches that stably transfected PGCs have not been obtained (page 20, line 13). Neither the specification nor the art teach obtaining stably transfected EG or ES cells or making transgenic birds using EG or ES cells comprising an exogenous transgene as claimed. Given the teachings in the specification taken with what was known in the art, it would have required one of skill undue experimentation to determine how to obtain a stably transfected PGC, EG or ES cell, the specific transgene construct required to make a transgenic avian with an exogenous transgene such that the exogenous protein could be isolated or that the exogenous protein altered the phenotype of the avian. Therefore, the specification does not enable making a stably transfected EG cell or making transgenic avians using EG or ES cells with an exogenous transgene as claimed.

The specification does not enable one of skill to determine the limitation in claim 3. The "maximal amounts of said growth factors range from about two times to one hundred times said minimum amounts" is not enabled because the "minimum" and "maximum" amounts are not defined in the specification and the specification does not teach the "minimum" and "maximum" amount for each growth factor that is required to obtain EG cells or any other cell of interest.

The specification does not enable one of skill to obtain the EG cell line P102896 (claim 24).

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required. Furthermore, unless deposit was made at or before the time of filing, a declaration filed under 37 C.F.R. 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is the same as that described in the specification, and establish that the deposited material was in applicant's possession at the time of filing. In re Lundak, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that,

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years of 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of the deposit was made and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

As required under 37 C.F.R. § 1.809(d), the specification shall contain: (1) the accession number for the deposit; (2) the date of deposit; (3) a description of the deposited biological material sufficient to identify it and to permit its examination; and (4) the name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specification does not provide adequate guidance for one of skill to distinguish PGCs and EG cells. It is unclear if PGCs are cells that can become germline cells only or if PGCs can become germline cells and somatic cells. Similarly, it is unclear if EG cells are a subpopulation of PGCs that can become germline cells and somatic cells or if EG cells are different than PGCs because PGCs cannot become somatic cells. The specification states EG cells become somatic and germline cells (page 22, line 15). The specification states PGCs migrate to the gonads (page 19, line 5) but does not exclude them from also becoming somatic cells. The specification states EG cells are identified using antibodies such as SSEA-1, SSEA-3, MC-480 and EMA-1 (page 21, last paragraph; page 22, first paragraph); however, PGCs also are indicated using the same antibodies. In addition, it is unclear how the EG cells claimed differ from ES cells known in the

art (see art rejections below). Overall, the specification does not distinguish PGCs from EG cells in such a way that the difference in structure or function of the cells can be determined.

Claim 3 is indefinite because the phrase the "maximal amounts of said growth factors range from about two times to one hundred times said minimum amounts" is unclear. The phrase "said minimum amounts" lacks antecedent basis within the claim or in parent claim 1. The "minimum" and "maximum" amounts are not defined in the specification and the specification does not teach the "minimum" and "maximum" amount for each growth factor that is required to obtain EG cells or any other cell of interest. Therefore, the metes and bounds of the claim cannot be determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1, 3-6, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (Chang et al., 1995, Cell Biol. International, Vol. 19, pages 143-149).

The following rejection is based on the fact that EG cells claimed may also be PGCs (see 112/2nd) and that the culturing method in claim 1 "may be performed in the absence of feeder cells". The phrase "may be performed in the absence of feeder cells" is an intended use and does not indicate that the cells are cultured in the absence of feeder cells. Therefore, the cells may also be cultured in the presence of feeder cells.

Chang teaches isolating PGCs from the heart of stage XIII and XIV chicken embryos and culturing the cells for 5 days in the presence of 10 units/ml of LIF, 10 ng/ml bFGF, 10 ng/ml IGF and feeder cells (page 143, col. 2, 2nd paragraph through page 144, col. 2, 2nd full paragraph). PGCs were identified using PAS staining (page 144, col. 2, last full paragraph). Five days is considered a prolonged period (claim 1). The method of Chang does not differ from the method claimed (claims 1 and 3-6) because the EG cells obtained may be PGCs and because the cells may be cultured in the presence of feeder cells. Identifying PGCs expressing PAS as taught by Chang is equivalent to identifying EG cells as claimed (claim 1). The limitation of "the maximal amount of said growth factors" in claim 3 is an intended use because it not required in the claim; therefore, the limitation does not bear patentable weight in determining art. The PGCs of Chang do not differ from the EG cells claimed (claims 21 and 22) because EG cells may be PGCs (112/2nd) and because the method used by Chang differs from the method claimed only in the addition of SCF to the media. It is not readily apparent that SCF would significantly alter the phenotype of the PGCs to distinguish the cells claimed from those taught by Chang. Thus, Chang anticipates the claims.

4. Claims 1, 3-11, 14-16 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Pain (7-25-96, Development, Vol. 122, pages 2239-2348, UnCover online at http://uncweb.carl.org/uncover/unchome.html) as evidenced by Simkiss (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137).

Pain was available to the public and indexed in UnCover on 7-25-96. UnCover is an article database and article delivery service (see http://uncweb.carl.org/uncover/unchome.html). Therefore, Pain was available to the public and indexed through UnCover over a year before the effective filing date of the instant invention and is a 102(b). See the basis of the rejection below.

5. Claims 1, 3-11, 14-16 and 20-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Pain (Aug. 1996, Development, Vol. 122, pages 2239-2348) as evidenced by Simkiss (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137).

Pain teaches isolating cells from the blastoderm of a stage X chicken embryo, culturing the cells for more than 160 days in the presence of 10 ng/ml bFGF, 20 ng/ml IGF, 1% vol/vol SCF, 1% vol/vol LIF without feeder cells (page 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10; 2341, col. 2, paragraph 4). The cells expressed EMA-1, SSEA-1 and SSEA-3 for 160 days (page 243, col. 2, last 2 sentences). Simkiss confirms that isolating cells from the blastoderm of stage X chicken embryos of Pain results in isolating some PGCs as claimed by teaching that stage X chicken embryos contain PGCs (page 111, Fig. 4.1, top

panel). Pain teaches introducing the cultured PGCs into stage X chicken embryos and obtaining germline and somatic cell chimeras (page 2341, col. 1, paragraph 2; page 2346, col. 2, line 8). The ES cells of Pain are EG cells as claimed because they produce germline and somatic cell chimeric chicks.

Identifying ES cells expressing EMA-1, SSEA-1 and SSEA-3 and cells that provide germline and somatic cell chimeras as taught by Pain is equivalent to identifying EG cells as claimed (claims 1, 9 and 10). The limitation of "the maximal amount of said growth factors" in claim 3 is an intended use because it not required in the claim; therefore, the limitation does not bear patentable weight in determining art. Injecting cells into the subgerminal cavity of a stage X chicken embryo as taught by Pain is equivalent to a injecting a recipient blastoderm (claims 10 and 20). Thus, Pain anticipates the claims.

6. Claims 1, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Petitte (Petitte et al., US Patent 5,656,479, Aug. 12, 1997).

Petitte teaches isolating avian embryonic stem cells from the blastoderm of a stage IX-XIV chicken embryo, culturing the cells and obtaining embryonic cell phenotype (see claims 1-3 of '479). Identifying cells that have the ES cell phenotype as taught by Petitte is equivalent to identifying EG cells as claimed (claim 1). The avian ES cells of Petitte do not differ from the EG cells claimed (claims 21 and 22) because EG cells may be ES cells (112/2nd), because the ES cells of Petitte are isolated from IX-XIV embryos, have an ES cell phenotype and are cultured in the presence of LIF and because the method of claim does not require culturing the cells in the

absence of feeder cells. It is not readily apparent that the method of Petitte and the claimed method are significantly different such that the ES cells of Petitte are phenotypically different than the EG cells claimed. Thus, Petitte anticipates the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pain (Aug. 1996, Development, Vol. 122, pages 2239-2348) as evidenced by Simkiss (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137).

Pain teaches isolating cells from the blastoderm of a stage X chicken embryo, culturing the cells for more than 160 days in the presence of 10 ng/ml bFGF, 20 ng/ml IGF, 1% vol/vol SCF, 1% vol/vol LIF without feeder cells (page 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10; 2341, col. 2, paragraph 4). The cells expressed EMA-1, SSEA-1 and SSEA-3 for 160 days (page 243, col. 2, last 2 sentences). Simkiss confirms that isolating cells from the blastoderm of stage X chicken embryos of Pain results in isolating some PGCs as claimed by teaching that stage X chicken embryos contain PGCs (page 111, Fig. 4.1, top

panel). Pain teaches introducing the cultured PGCs into stage X chicken embryos and obtaining germline and somatic cell chimeras (page 2341, col. 1, paragraph 2; page 2346, col. 2, line 8). The ES cells of Pain are EG cells as claimed because they produce germline and somatic cell chimeric chicks. Identifying ES cells expressing EMA-1, SSEA-1 and SSEA-3 and cells that provide germline and somatic cell chimeras as taught by Pain is equivalent to identifying EG cells (claim 1). Pain does not teach using 0.00625 U/μl LIF, 0.25 pg/μl bFGF, 0.5625 pg/μl IGF, 5.0 pg/μl SCF.

However, Pain taught varying the culture conditions required to obtain EG/ES cells (page 2341, col. 2, "Requirements of specific growth factors and cytokines for CEC and QEC cells"). One of ordinary skill in the art at the time the invention was made would have motivated to use 0.00625 U/μl LIF, 0.25 pg/μl bFGF, 0.5625 pg/μl IGF, 5.0 pg/μl SCF to optimize the conditions required to obtain EG/ES cells.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-5, 14-16 and 20-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 of '569 are obvious variants of claims 1-5, 14-16 and 20-22 in the instant application.

9. Claims 1 and 6-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 in view of Pain (Pain et al., 1996, Development, Vol. 122, pages 2239-2348).

The claims of '569 are directed toward culturing pure PGCs for at least 14 days. The claims do not recite the limitations of maintaining the cells for at least 25 days or 4 months. However, Pain taught culturing avian embryonic cells for at least 160 days (page 2345, col. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed invention in '569 to maintain the PGCs for at least 25 days or 4 months. One of ordinary skill would have been motivated to maintain the PGCs for at least 25 days or 4 months to increase the availability of the PGCs.

10. Claims 1-5, 21 and 22 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 8 and 29-40 of copending Application No. 09/127,624. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 4, 5, 7, 8 and 29-32 are directed toward a method of culturing a pure population of avian PGCs in a culture medium for at least 14 days. Claims 33-40 are directed toward a purified population of avian PGCs in culture media such that the PGCs are maintained for at least 14 days. The instant claims are directed toward a method of culturing PGCs and obtaining EG cells (claims 1-5) and EG cell lines (claims 21 and 22); however, the difference between EG cells and PGCs cannot be determined (see 112/2nd above). The limitation of culturing cells "may be in the absence of feeder cells" in the instant claims may not occur. Therefore the claims of '624 are obvious variants of the claims in the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1 and 6-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 8 and 29-40 of U.S. Patent No. 09/127624 in view of Pain et al.

Claims 1, 4, 5, 7, 8 and 29-32 of '624 are directed toward a method of culturing a pure population of avian PGCs in a culture medium for at least 14 days. Claims 33-40 of '624 are directed toward a purified population of avian PGCs in culture media such that the PGCs are maintained for at least 14 days. The instant claims are directed toward a method of culturing

PGCs for at least 25 days or 4 months and obtaining EG cells (claims 1 and 6-8); however, the difference between EG cells and PGCs cannot be determined (see 112/2nd above). The limitation of culturing cells "may be in the absence of feeder cells" in the instant claims may not occur. The claims of '624 do not recite the limitations of maintaining the cells for at least 25 days or 4 months.

However, Pain taught culturing avian embryonic cells for at least 160 days (page 2345, col. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed invention in '569 to maintain the PGCs for at least 25 days or 4 months. One of ordinary skill would have been motivated to maintain the PGCs for at least 25 days or 4 months to increase the availability of the PGCs. Therefore the claims of '624 taken with Pain are obvious variants of the claims in the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12 and 13 appear to be free of the prior art of record because the prior art of record did not teach or suggest culturing avian PGCs in a culture medium comprising LIF, bFGF, SCF and IGF in amounts sufficient to maintain said PGCs for a prolonged periods and transfecting/transforming the cells with a nucleic acid. Claims 17-19 appear to be free of the prior art of record because the prior art of record did not teach or suggest making a chimeric avian comprising culturing avian PGCs in a culture medium comprising LIF, bFGF, SCF and IGF in

amounts sufficient to maintain said PGCs for a prolonged periods, transfecting/transforming the cells with a nucleic acid and transferring the cells into a recipient embryo and selecting chimeric avians with the desired PGC phenotype. Claim 23 appears to be free of the prior art of record because the prior art of record did not teach or suggest making an avian EG cell line transfected/transformed with a nucleic acid. Claim 24 appears to be free of the prior art of record because the prior art of record did not teach or suggest the EG cell line P102896.

***Conclusion***

This action is non-final. No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-0196.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER